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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,349	03/16/2001	Wolfgang Rohde	07258-022001	4891

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,349	ROHDE ET AL.	
	Examin r	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 December 2003 has been entered.

2. Claims 28-37 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 28-29 and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Lucas (WO 97/06669) is withdrawn in light of Applicant's amendments to exclude TMV movement proteins.

Claim Rejections - 35 USC § 112

5. Claims 28-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "wherein the virus-encoded transport protein is not tobacco mosaic virus (TMV) movement protein or a derivative thereof" in lines 17-18 of claim 28. Thus, such a phrase

constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

6. Claims 28-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing potato plants that are tolerant of drought, fungal infection and salt by transformation with a nucleic acid encoding the pr17 protein operably linked to an N-terminal extension of SEQ ID NO:1, does not reasonably provide enablement for a method of producing plants by transformation with a nucleic acids that encodes a "virus-encoded transport protein" to produce any and all plant species that are tolerant of drought, fungal infection, salt and temperature, wherein the transport protein is not TMV movement protein or derivatives thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the rejection set forth in the Office action mailed 2 July 2003. Applicant's arguments and The Declaration of Dr. Wolfgang Rohde, both filed 22 December 2003, have been fully considered but they are not persuasive.

The claims are broadly drawn to a method of using a multitude of DNA molecules that encode a "virus-encoded" movement protein to produce plants that are tolerant of drought, fungal infection, salt and temperature, wherein the movement protein is not tobacco mosaic virus (TMV) movement protein or derivatives thereof.

The instant specification, however, only provides guidance for production of a vector encoding the pr17 protein operably linked to an N-terminal extension of SEQ ID NO:1 (example 1); transformation of the vector into potato (example 2); Western blotting of extracts from

transformed plants to show they produced the pr17 protein (example 3); and demonstrating that the transgenic plants are resistant to *Phytophthora infestans* (examples 4 and 6), drought (example 5), and salt (example 7).

The instant specification fails to provide guidance for nucleic acids encoding other derivatives of pr17 or other viral movement proteins and fails to provide guidance for using those nucleic acids to produce plants that are tolerant of drought, fungal infection, salt and temperature. The instant specification also fails to provide guidance for derivatives of TMV movement protein. The specification also fails to provide guidance for plants other than potato that are tolerant of drought, fungal infection, salt and temperature.

Tacke et al (1996, Nature Biotechnol. 14:1597-1601) teach that potato plants transformed with a nucleic acid encoding wild-type pr17 or pr-17 with an N-terminal extension other than SEQ ID NO:1 were not resistant to potato virus X (pg 1596, paragraph spanning the columns).

Additionally, not all plants are susceptible to infection by *Phytophthora infestans*, so it is unclear how transformation with any protein could increase the tolerance of a plant to infection by *Phytophthora infestans* or how such an increase could be measured in such plants.

Given the limited teachings in the specification showing production of disease resistance in potato with a single nucleic acid and the failure of the instant specification to teach nucleic acids encoding proteins other than pr17 + SEQ ID NO:1, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those that also confer tolerance to drought, fungal infection, salt and temperature.

Given the specificity of protein-protein interaction and given that potato leaf roll virus does not infect all plants, it is unclear that a nucleic acid encoding pr17 + SEQ ID NO:1 would work in other plants, particularly distantly related ones like cereals.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

The Declaration of Dr. Wolfgang Rohde (alos summarized in the repsonse, on pg 4-5) states that he has observed that generally tolerance to drought and extreeme temperatures go hand in hand and that because they have demonstrated that plants transformed with [a nucleic acid encoding] viral transport protein are tolerant to drought, they would be tolerant to extreme temperatures. He urges that both monocots and dicots can be transformed by the appropriate pr17 or pr17-N constructs and result in plants with increased tolerance to drought, fungal infections and extreme temperatures. He urges that other derivatives of pr17 or different movement proteins of other plant viruses, whether wild-type or mutant, should confer tolerance to drought, fungal infections and extreme temperatures.

This is not found persuasive. Tacke et al (1996, Nature Biotechnol. 14:1597-1601) teach that potato plants transformed with a nucleic acid encoding wild-type pr17 or pr-17 with an N-terminal extension other than SEQ ID NO:1 were not resistant to potato virus X (pg 1596, paragraph spanning the columns). Thus, it remains unclear that a nucleic acid encoding pr17 + SEQ ID NO:1 would work in other plants, particularly distantly related ones like cereals. Dr. Rodhe's statements are unsupported assertions. Neither the specification nor the prior art teaches nucleic acids encoding derivatives of pr17 other than pr17-N nor do they teach derivatives of

TMV movement protein, making it unclear what is excluded from the invention. The specification does not teach what other nucleic acids encoding viral transport protein would work in the instant invention.

Applicant's aruments with respect to the correlation between tolerance to drought and to extreme temperatures is accepted.

7. Claims 28-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 2 July 2003. Applicant's arguments filed 22 December 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to use of any of a multitude of nucleic acids that encode "derivatives" of potato leaf roll virus (PLRV) transport protein pr17, wherein the "derivatives" are not TMV movement protein or a "derivative" thereof. In contrast, the specification only describes a coding sequence that encodes pr17-N. Derivatives of TMV movement protein are not described; thus, it is not clear if pr17-N is a "derivative" of TMV movement protein. Applicant does not describe other nucleic acids encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Because the sequences are not described, the method of using the sequences to produce plants with increased tolerance to stress is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant urges that sufficient, relevant, identiying structural and physicai characteristics of plant viral transport proteins are disclosed on page 7-8, including citation of references whose content is incorporated by reference. The structural and physical characteristics of the viral transport protein pr17 are disclosed on page 8 at lines 7-21 of the specification, which describes an amino terminal domain for homopolymer formation, a carboxyterminal domain for binding single-stranded amino acids, and plasmodesmatal localization of infection-derived and transgenic pr17 in phloem cells. Applicant urges that the specification further discloses that expression of WT and mutated PLRV transport proteins (PLRV-TPS) confers broad-spectrum resistance to viruses and increases in intracellular sugar and starch concentrations (page 8 at lines 21-27) (repsone pg 5).

This is not found persuasive: none of the cited pages describe any derivative of pr17 other than pr17-N. None of the references incorporated by reference were sent, so they could not be considered, but based on their citation in the specification, none appears to describe nucleic acid encoding other viral-encoded transport proteins or derivatives of pr17 other than pr17-N. It is also it is not clear if pr17-N is a "derivative" of TMV movement protein and thus excluded from the claims.

8. Claims 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as

the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 2 July 2003. Applicant's arguments filed 22 December 2003 have been fully considered but they are not persuasive.

Claim 28, line 18 and claim 29, lines 2-3, are indefinite in their recitation of "derivative thereof". The manner in which the derivatives vary from TMV movement protein or pr17 is unclear.

Applicant urges that one of skill in the art would interpret "a derivative thereof" to include any pr17 derivative that, when expressed in a plant, would confer increased tolerance against drought, fungal infections, incraesed salt concentrations or extreme temperature and that the specification provides the example of pr17-N. Furthermore, Applicant urges that one of skill in the art could make derivatives of pr17 and test them using the teachings of the specification (response pg 6-7).

This is not found persuasive. It is unclear how derivatives of pr17 differ in sequence from pr17. From Applicant's response it appears that they consider anything that works, regardless of sequence or source, to be a derivative of pr17; however, it is unclear what the sequence of those derivatives are. Thus, the metes and bounds of the claimed invention are unclear.

Claim 28 is indefinite in its recitation of "nucleic acid which encodes a virus-encoded transport protein" in part (a). Does this mean the plant is being transformed with a virus or does it simply mean the nucleic acid encodes a viral transport protein?

Applicant urges that pg 1, lines 10-11, teach that the plant is transformed with a nucleic acid that encodes a viral transport protein (response pg 7).

This is not found persuasive because pg 1, lines 10-11, uses the rejected phraseology without definition. Thus, it remains unclear if the plant is being transformed with a virus or does it simply mean the nucleic acid encodes a viral transport protein. OIF applicant intends the phrase to mean the plant is transformed with a nucleic acid that encodes a viral transport protein, it is suggested that "viral-encoded" be replaced with --viral--.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 28-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Tacke et al (1996, Nature Biotechnol. 14:1597-1601) and Herbers et al (1997, Plant J. 12:1045-1056) in view of Lucas (WO 97/06669).

The claims are drawn to a method of producing potato plants transformed with a nucleic acid encoding the potato leaf roll virus movement protein pr17 with and without a hydrophilic N-terminal extension of SEQ ID NO:1, wherein the method involves testing the transgenic plants for increased tolerance to extreme temperature and other stresses.

Tacke et al teach a method of producing potato plants transformed with a nucleic acid encoding the potato leaf roll virus movement protein pr17 with and without a hydrophilic N-terminal extension of SEQ ID NO:1; this method involves transforming calli and regenerating them into plants (pg 1597, right column, and pg 1600, left column, paragraph 2). The

transformed plants were also vegetatively propagated (pg 1596, left column, paragraph 2), making plants from the transformed plants. Tacke et al do not disclose testing the transgenic plants for increased tolerance to extreme temperature.

Herbers et al teach a method of producing tobacco plants transformed with a nucleic acid encoding the potato leaf roll virus movement protein MP17 with the N-terminal extension taught by Tacke et al (pg 1046, right column, paragraphs 2-3, and pg 1054, left column, paragraph 2). MP17 is another name for pr17. Because these plants are notably shorter than control plants (Fig. 1), they would have increased tolerance to drought (due to lower surface area). Herbers et al do not disclose testing the transgenic plants for increased tolerance to extreme temperature.

Lucas teaches a method of producing tobacco plants by transformation with nucleic acids encoding the wild-type or mutant movement protein of tobacco mosaic virus (pg 23-30). The method involved testing the regenerated transgenic plants under extreme temperatures (pg 23 and 28-29; Table 9); the tested transgenic plant was "used" to produce a plant, itself. The plants showed essentially normal growth (pg 28). Because the method of producing these plants involves the same steps as the instantly claimed methods, Lucas inherently teaches a method of producing plants with increased tolerance of fungi, including *Phytophthora infestans*.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of producing tobacco plants transformed with a nucleic acid encoding the potato leaf roll virus movement protein pr17 (MP17) with and without a hydrophilic N-terminal extension of SEQ ID NO:1 as taught by Tacke et al and Herbers et al, to test the transgenic plants for increased tolerance to extreme temperature as described in Lucas. One of ordinary skill in the art would have been motivated to do so because of the desirability of

having plants with increased tolerance to extreme temperature. Furthermore, it would be obvious to test the plants for increased tolerance to other stresses, including increased salt, drought and pathogen tolerance, because plants transformed with a nucleic acids encoding TMV movement protein exhibited a decrease in translocation of assimilates, from source leaves (Lucas, pg 3, lines 20-22), because tolerance to drought goes hand in hand with tolerance to extreme temperatures, and because many pathogens make use of plant transport mechanisms for spread through the plant.

Conclusion

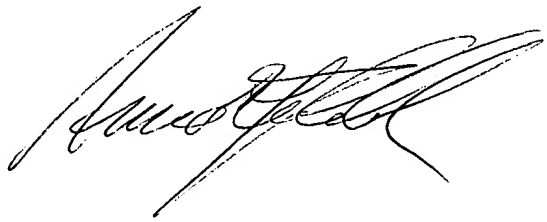
11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
February 12, 2004



ANNE KUBELIK
PATENT EXAMINER